DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 31, 2015

Biogenesis Co., Ltd.
c/o Ms. Priscilla Chung
LK Consulting Group USA, Inc.
2651 East Chapman Avenue Suite 110
Fullerton, California 92831

Re: K142813
Trade/Device Name: Biogenesis™ Implant System - Kisses
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: June 26, 2015
Received: July 01, 2015

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K142813

Device Name
Biogenesis Implant System –Kisses

Indications for Use *(Describe)*

The Biogenesis Implant System –Kisses is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.
The Biogenesis Implant System – Kisses is for single and two stage surgical procedures. It is for delayed loading.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary
(K142813)

This summary of 510(K) is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 07/30/2015

1. Applicant / Submitter

Biogenesis Co., Ltd.
Mecha Zone #1109, SK Techno Park,
50, Wanam-Ro, Seongsan-Gu,
Changwon-Si, Gyeongsangnam-Do,
Republic of Korea, 642-971
Tel: +82-55-607-0345 Fax: +82-55-607-0347

2. Submission Correspondent

Priscilla Chung
LK Consulting Group USA, Inc.
2651 E Chapman Ave. Ste 110, Fullerton CA 92831
Phone: 714.202.5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

- Trade Name: Biogenesis™ Implant System - Kisses
- Common Name: Dental Implant
- Classification Name: Endosseous Dental Implant
- Product Code: DZE, NHA
- Classification regulation: 21CFR872.3640

4. Predicate Device:

- **Primary Predicate Device:**
  TS Fixture System by Ossetem Implant Co., Ltd. (K121995)
- **Reference Predicate Devices:**
  Dentium Co., Ltd Implantium by Dentium Co., Ltd. (K041368)
  Implantium Abutments by Dentium Co., Ltd. (K052823)
  EZ Plus Implant System by Megagen Co., Ltd. (K070562)

5. Description:

The Biogenesis™ Implant System – Kisses is a dental implant system made of titanium intended to be surgically placed in the bone of the upper or lower jaw arches. This product is a substructure of a dental implant system to replace a single tooth, partial tooth and the lost root of edentulous patients. It consists of the hex part to be coupled to the superstructure, the single thread part to be fixed to the bone, and the cutting edge part with the self-tapping function.

The Biogenesis™ Implant System offers bone level implants in the size range of 3.8 – 5.5 mm diameter with 7 – 14.5mm length.

- **Diameter:** 3.8mm / 4.2mm / 4.6mm / 5.1mm / 5.5mm x **Length:** 7mm / 8mm / 9.5mm / 11mm / 12.5mm / 14.5mm

The Biogenesis™ Implant System also offers the following components.

- Duplex Abutment
- Duplex Milling Abutment
- Simplex Abutment
- Temporary Abutment
- Solid Screw Abutment
- Ball Abutment
- Ball Cap

The implants are intended for use with straight implant only and that only straight implants are included in the submission.

6. Indication for use:

The Biogenesis Implant System - Kisses is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The Biogenesis Implant System is for single and two stage surgical procedures. It is intended for delayed loading.

7. Basis for Substantial Equivalence

The Biogenesis Implant System – Kisses is substantially equivalent to previously marketed devices as presented in the comparison tables below.

The subject device is similar to the predicate devices based on the intended use, the principle of operations, the materials, the surface treatment, the size range and the technological characteristics. The verbiage of the Indications for Use of the subject device is slightly different than that of the declared predicates; however, these slight differences in wording does not change the intended use of the subject device has

compared to the declared predicate. In addition, the external design of the subject device is slightly different from the predicate devices; however, the performance testing provided in this 510k submission supports that the subject device is substantially equivalent to the predicate devices.

Comparison Chart

1) Fixture

	Subject Device	Primary Predicate Device	Reference Predicate Device
510(K) Number	N / A	K121995	K041368
Device Name	Biogenesis Implant System - Kisses	TS Fixture System	Dentium Co., Ltd Implantium
Manufacturer	Biogenesis	Osstem	Dentium
Type	Internal hex	Internal hex	Internal hex
Design & Size Range	 Diameter: 3.8 – 5.5 mm Length: 7 – 14.5 mm	 Diameter: 3.5 – 5.0 mm Length: 7-15 mm	 Diameter: 3.4 – 5.8 mm Length: 7-15 mm
Indications for Use	The Biogenesis Implant System - Kisses is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The Biogenesis Implant System - Kisses is for single and two stage surgical procedures. It is for delayed loading	The TS fixture system is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ts fixture system is compatible with abutment in the et/ss implant system	The dentium co., ltd. Implantium is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. This may be accomplished by either a two-stage surgical procedure or a single surgical procedure. If a single surgical procedure is used, single or multiple implants may be inserted (type i, or iii bone) provided good initial stability (> 40 ncm) is achieved. Not intended for immediate loading.
Material Composition	Ti Gr.4	Ti Gr.4	Ti Gr.4
Surface Treatment	SLA Treatment	SLA Treatment	SLA Treatment
Sterile	Yes	Yes	Yes
Sterilization Method	Gamma	Gamma	Gamma

2) Abutment

	Subject Device	Reference Predicate Device	Reference Predicate Device
510(K) Number	N / A	K052823	K070562
Device Name	Biogenesis Implant System - Kisses	Implantium Abutments	EZ Plus Implant System
Manufacturer	Biogenesis	Dentium	Megagen
Type	Internal	Internal	internal
Indications for Use	The Biogenesis Implant System - Kisses is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The Biogenesis Implant System - Kisses is for single and two stage surgical procedures. It is for delayed loading	The implantium abutments are intended to be used with the im-plantium root-form endosseous dental implant to aid in prosthetic rehabilitation including overdenture retention. After the root-form endosseous dental implant is surgically placed, the endosseous dental implant abutment device is attached to it.	The ez plus implant systems are intended to be surgically placed in the upper or lower jaw to support prosthetic devices, such as artifical teeth and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure. Large angle abutments (e.G. 25 degree) on small diameter implants of the ez plus internal connection system are intended for the anterior region of the mouth and not intended for use in the posterior region of the mouth due to limited strenth of the implant
Abutment 1– Duplex Abutment			
<Duplex Abutment> Design & Size Range	 Hex & Non-Hex Diameter: 4.0mm - 6.5mm Post Height : 4.0mm - 7.0mm Gingival Height: 1mm – 7.0mm	 Hex & Non-Hex Diameter: 4.5mm - 6.5mm Post Height : 5.5mm Gingival Height: 1mm - 5.5mm	 Trip & Non-Trip Diameter: 4mm - 6mm Post Height : 5mm Gingival Height: 1mm - 5mm
Intended Use	Cement retained restoration	Cement retained restoration	Cement retained restoration
Material Composition	Ti Gr.4	Ti Gr.4	Ti Gr.4
Surface Treatment	Anodizing coloring – Gold color (Entire Body)	TiN coating – Gold color (Partly)	Anodizing coloring – Gold color(Entire Body)
Sterile	No	No	No
Abutment 2– Duplex Milling Abutment			
<Duplex Milling Abutment> Design & Size Range			

	Hex & Non-Hex Diameter: 4.0mm - 6.5mm Gingival Height: 1.5mm – 3.0mm	Hex & Non-Hex Diameter: 4.0mm - 6.5mm Gingival Height: 1.5mm – 3.0mm	Trip & Non-Trip Diameter: 5mm - 6mm Gingival Height: 1mm – 5mm
Intended Use	Cement retained restoration	Cement retained restoration	Cement retained restoration
Material Composition	Ti Gr.4	Ti Gr.4	Ti Gr.4
Surface Treatment	Anodizing coloring – Gold color(Entire Body)	TiN coating – Gold color (Partly)	Anodizing coloring – Gold color(Entire Body)
Sterile	No	No	No
Abutment 3– Simplex Abutment			
<Simplex Abutment> Design & Size Range	 Diameter: 4.0mm - 6.5mm Post Height : 4.0mm - 5.5mm Gingival Height: 1mm – 7.0mm	 Diameter: 4.5mm - 6.5mm Post Height : 5.5mm Gingival Height: 1mm - 5.5mm	 Diameter: 4mm - 6mm Post Height : 3.5 / 5mm Gingival Height: 1mm - 5mm
Intended Use	Cement retained restoration	Cement retained restoration	Cement retained restoration
Material Composition	Ti Gr.4	Ti Gr.4	Ti Gr.4
Surface Treatment	Anodizing coloring – Gold color(Entire Body)	TiN coating – Gold color (Partly)	Anodizing coloring – Gold color(Entire Body)
Sterile	No	No	No
Abutment 4– Solid Screw Abutment			
<Solid Screw> Design & Size Range	 Diameter: 4.8mm Post Height : 4.0mm – 7.0mm Gingival Height: 1.0mm – 7.0mm	 Diameter: 4.5mm - 6.5mm Post Height : 5.5mm Gingival Height: 1mm - 5.5mm	 Diameter: 4mm - 6mm Post Height : 3.5 / 5mm Gingival Height: 1mm - 5.0mm
Intended Use	Cement retained restoration	Cement retained restoration	Cement retained restoration
Material Composition	Ti Gr.4	Ti Gr.4	Ti Gr.4
Surface Treatment	Anodizing coloring – Gold color(Entire Body)	TiN coating – Gold color (Partly)	Anodizing coloring – Gold color(Entire Body)
Sterile	No	No	No
Abutment 5– Temporary Abutment			
<Temporary Abutment> Design & Size Range	 Hex & Non-Hex		 Hex & Non-Hex

	Diameter: 4.0 / 4.5mm Gingival Height: 1mm	Hex & Non-Hex Diameter: 4.5mm Gingival Height: 1mm	Diameter: 4mm / 4.5mm Gingival Height: 1.5mm
Intended Use	To manufacture temporary prostheses	To manufacture temporary prostheses	To manufacture temporary prostheses
Material Composition	Ti Gr.4	Ti Gr.4	Ti Gr.3
Surface Treatment	No	No	No
Sterile	No	No	No
Material Composition	Delrin 500P NC010	Delrin 500P NC010	Delrin 500P NC010
Surface Treatment	No	No	No
Sterile	No	No	No
Abutment 6– Ball abutment			
<Solid Screw> Design & Size Range	 Diameter: 3.0, 3.5mm Gingival Height: 0.5mm – 7mm	 Diameter: 3.3mm –3.5mm Gingival Height: 0mm - 5mm	
Intended Use	Cement retained restoration	Cement retained restoration	
Material Composition	Ti 6Al 4V ELI, Gr.23	Ti Gr.4	
Surface Treatment	Anodizing coloring – Gold color(Entire Body)	No	
Sterile	No	No	

3) Screws

	Subject Device	Reference Predicate Device
510(K) Number	N / A	K052823
Device Name	Biogenesis Implant System - Kisses	Implantium Abutments
Manufacturer	Biogenesis	Dentium
Abutment Screw		
<Abutment Screw> Design & Size Range		
Intended Use	To connect the abutment to the fixture	To connect the abutment to the fixture
Material Composition	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23
Surface Treatment	No	No
Sterile	No	No
Cover Screw		
<Cover Screw> Design & Size Range		

Intended Use	To provide sealing effect for fixture	To provide sealing effect for fixture
Material Composition	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23
Surface Treatment	Anodizing coloring(Entire Body)	Anodizing coloring(Entire Body)
Sterile	Yes	Yes
Sterilization Method	Gamma	Gamma
Healing Screw		
<Healing Screw> Design & Size Range		
Intended Use	To help the soft tissue of gum naturally formed.	To help the soft tissue of gum naturally formed.
Material Composition	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23
Surface Treatment	No	No
Sterile	Yes	Yes
Sterilization Method	Gamma	Gamma

8. Non-Clinical Testing

Various performance testing has been performed on the Biogenesis Implant System–Kisses and the test results met the pre-set criteria. Testing included:

- Sterilization validating testing according to ISO 17665-1/2 and ANSI/AANI ST79
- Shelf life testing according to ASTM F1980
- Biocompatibility testing per ISO 10993-1
- Conformance to FDA Guidance Document for Endosseous Dental Implants and Abutments

There might be some differences in sterilization parameters, shelf life and manufacturing processes between the subject device and the predicate devices, however, the test results supported that the subject device is substantially equivalent to the predicate devices.

9. Conclusion

The subject device and the predicate devices have the same intended use and have similar technological characteristics.
Overall, the Biogenesis Implant System –Kisses has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same material and the surface treatment.

Based on the similarities, we conclude that the Biogenesis Implant System –Kisses is substantially equivalent to the predicate devices.